

LACHMAN CONSULTANT SERVICES, INC.
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

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August 31, 2000

OVERNIGHT COURIER 8/31/00

Dockets Management Branch
Food and Drug Administration (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

This petition is submitted in quadruplicate pursuant to 21 CFR 10.30 and in accordance with the regulations at 21 CFR 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Glucophage® (Metformin HCl) Tablets, 625 mg and 750 mg, (NDA No. N20357), by Bristol-Myers Squibb Co., have been voluntarily withdrawn or withheld from sale for safety or efficacy reasons.

B. Statement of Grounds

The Food and Drug Administration maintains a list of drug products which are eligible for submission as abbreviated new drug applications in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("The Orange Book"). The current (20th) edition of the Orange Book includes Glucophage® Tablets, 625 mg and 750 mg in the Discontinued Drug Product List section (applicable page attached). A listing in this section of the Orange Book indicates that those drug products designated by the symbol "***" have already been provided with a determination as to whether the drug products were not marketed or withdrawn for safety or efficacy reasons. The listing for Glucophage® (Metformin HCl) Tablets, 625 mg and 750 mg are not designated by the symbol "***". Therefore, it appears that a determination has not been made as to whether the listed drug has been voluntarily withdrawn for safety or effectiveness reasons.

Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug application for the reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a

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determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161{a}{1}).

As stated, Bristol-Myers Squibb's Glucophage® (Metformin HCl) Tablets, 625 mg and 750 mg, are not available for sale in the marketplace. Because there is no current commercial distribution of this drug product and because this drug product is listed in the Discontinued Drug Product List section, it is requested that the FDA determine whether Bristol-Myers Squibb's decision not to market Glucophage® (Metformin HCl) Tablets, 625 mg and 750 mg was for reasons of safety or effectiveness.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 CFR 25.31.

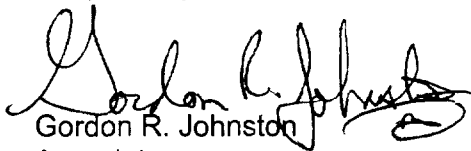
D. Economic Impact

Pursuant to 21 CFR 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided if so requested.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,


Gordon R. Johnston
Associate

Attachment: Discontinued Drug Product List Section Regarding: Glucophage® Tablets, 625 mg and 750 mg

cc: Nasser Mahmud (OGD)
Leon Lachman, Ph.D. (LCS)

36k0244a

DISCONTINUED DRUG PRODUCT LIST

6-113

METAPROTERENOL SULFATESOLUTION; INHALATION
METAPROTERENOL SULFATE
DEY

0.33%

0.5%

5%

MORTON GROVE

5%

SYRUP; ORAL
METAPROTERENOL SULFATE
MORTON GROVE

10MG/5ML

TABLET; ORAL
METAPROTERENOL SULFATE
AM THERAP

10MG

20MG

ROSEMONT

10MG

20MG

N71806 001
AUG 05, 1988
N71805 001
AUG 05, 1988
N70805 001
AUG 17, 1987
N72190 001
JUN 07, 1988N71656 001
OCT 13, 1987N72054 001
JUN 23, 1988
N72055 001
JUN 23, 1988
N71013 001
JAN 25, 1988
N71014 001
JAN 25, 1988METARAMINOL BITARTRATEINJECTABLE; INJECTION
METARAMINOL BITARTRATEAM PHARM PARTNERS
ELKINS SINN
SEARLEEQ 10MG BASE/ML
EQ 10MG BASE/ML
EQ 10MG BASE/ML
EQ 20MG BASE/MLN80431 001
N83363 001
N86418 001
N86418 002METFORMIN HYDROCHLORIDETABLET; ORAL
GLUCOPHAGE

BRISTOL MYERS SQUIBB 625MG

750MG

N20357 003
NOV 05, 1998
N20357 004
NOV 05, 1998METHACYCLINE HYDROCHLORIDECAPSULE; ORAL
RONDONMYCIN
WALLACE LABSEQ 140MG BASE
EQ 280MG BASEN60641 001
N60641 002SYRUP; ORAL
RONDONMYCIN
WALLACE LABS

EQ 70MG BASE/5ML

N60641 003

METHADONE HYDROCHLORIDETABLET, DISPERSIBLE; ORAL
WESTADONE
EON2.5MG
5MG
10MG
40MGN17108 001
N17108 002
N17108 003
N17108 004METHAMPHETAMINE HYDROCHLORIDETABLET; ORAL
METHAMPEX
TEVA
METHAMPHETAMINE HCL
TEVA10MG
5MGN83889 001
N86359 001METHARBITALTABLET; ORAL
GEMONIL
ABBOTT

100MG

N08322 001

METHDILAZINETABLET, CHEWABLE; ORAL
TACARYL
WESTWOOD SQUIBB

3.6MG

N11950 009

METHDILAZINE HYDROCHLORIDESYRUP; ORAL
METHDILAZINE HCL
ALPHARMA

4MG/5ML

N87122 001

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Docket Markets Branch				<input type="checkbox"/> SAT		<input type="checkbox"/>	
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